



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,156	06/21/2005	Yoshio Tsujino	1422-0679PUS1	6601

2292 7590 09/04/2007
BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER

KOSAR, AARON J

ART UNIT	PAPER NUMBER
----------	--------------

1651

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

09/04/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/540,156

Applicant(s)

TSUJINO ET AL.

Examiner

Aaron J. Kosar

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 6-8 and 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 9 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 June 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date See Continuation Sheet.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :6/21/05; 9/21/05; 8/17/06; 10/17/06.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, claim 1-5 and 9-10, in the reply filed on June 11, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 6-8 and 11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on June 11, 2007.

Applicant's election of the species of "a neutral phenol oxidase having the properties (3)-(7) as recited in claim 2", corresponding to phenol oxidase I, is also acknowledged.

Claims 1-5 and 9-10 are pending and examined on the merits.

Specification

The disclosure is objected to because of the following informalities: The specification contains spelling errors, for example *F. veltypes* (page 4) is properly, *F. velutipes*.

Appropriate correction is required.

Information Disclosure Statement

The information disclosure statement filed 21 June 2005 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. The references have been placed in the application file, but information referred to therein (namely

Art Unit: 1651

documents JP-10-501173-A, and JP-2001-514513-A) has not been considered. WO-2004/020617-A1 has been considered to the extent of the English abstract. JP-09-206071-A and LEE, et al have been considered to the extent of the English abstracts, tables and figures.

Furthermore, the international search reports (ISRs) dated 01/06/2004, 5/17/2006, and 7/17/2006, were omitted from the previous PTO-1449 forms and have been made of record in the attached form PTO-892.

Drawings

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because figure 16 appears to depict a distinguishing feature critical to the invention, but is illegible. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The claimed invention is directed to non-statutory subject matter. **Claims 1-4** are directed to naturally occurring compositions, namely the claims do not require any physical transformation (eg. isolation, fractionation, separation, purification, or other manipulation of the enzyme) and the invention as claimed does not produce a useful, concrete, and tangible result.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ a specific strain of fungus (*Flammulina velutipes* IFO 30601). It is not clear if the written description is sufficiently repeatable to avoid the need for a deposit. Further it is unclear if the starting materials were readily available to the public at the time of invention. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of *Flammulina velutipes* IFO 30601. See 37 CFR 1.802.

The specification does not provide a repeatable method for obtaining *Flammulina velutipes* IFO 30601 and it is unclear if the organism is a readily available material. The product appears to be not reproducible, because it is unclear what comprises strain IFO 30601 and what effect, if any, it has on the claimed phenol oxidase enzyme synthesis and properties. Deposit of *Flammulina velutipes* IFO 30601 would satisfy the enablement requirements of 35 U.S.C. 112. The deposit criteria appear to not have been met particularly with criteria (c), (d), and (e), below, see 37 CFR 1.801- 37 CFR 1.809 FOR AFTER 1/1/90.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating

Art Unit: 1651

that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

- (a) during the pendency of this application, access to the invention will be afforded to one determined by the Commissioner to be entitled thereto;
- (b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;
- (d) a viability statement in accordance with the provisions of 37 CFR 1.807; and
- (e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803 - 37 CFR 1.809 for additional explanation of these requirements.

It appears that a deposit was made in this application as filed as noted on pages 7, 37, and 39 of the specification. However, it is not clear if the deposit meets all of the criteria set forth in 37 CFR 1.801-1.809. Applicant or applicant's representative may provide assurance of compliance with the requirements of 35 U.S.C § 112, first paragraph, in the following manner.

SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

A declaration by applicant, assignee, or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection and rejection based on a lack of availability of biological material.

1. Identifies declarant.
2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.
3. States that the deposited material has been accorded a specific (recited) accession number.
4. States that all restriction on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.
5. States that the material has been deposited under conditions that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C § 122.
6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit for the enforceable life of the patent, whichever period is longer.
7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

Art Unit: 1651

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 and 9-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term “phenol oxidase” is indefinite. The term is unclear, because phenol oxidase may have multiple meanings, each of which defines a distinct enzyme having separate status in the art and because the substrates disclosed (specification page 15) and claimed which define the enzyme appear to be from dissimilar/multiple enzymes; however, the claims must be drawn to a single invention, a neutral phenol oxidase. Among the enzymes classified by the International Union of Biochemistry and biology (IUBMB, <www.chem.qmul.ac.uk/iubmb/enzyme/EC1/>) and disclosed by Applicant which are most closely related to the claimed phenol oxidase (catechol oxidase (EC 1.10.3.1), an o-diphenol or polyphenol oxidase; laccase (EC 1.10.3.2), a p-diphenol oxidase; o-aminophenol oxidase (EC 1.10.3.4); monophenol monooxygenase (EC 1.14.18.1), also known as phenol oxidase; and the enzymes listed in the specification, page 3 lines 4-5), it is unclear if Applicant’s phenol oxidase is a single enzyme or multiple enzymes. Applicant claims a “phenol oxidase” similar in name to the enzyme identified by EC 1.14.18.1 but also having activity with enzymes of EC 1.10 that react with o-aminophenol, catechol, etc. as disclosed/claimed. As it is unclear if single or multiple enzymes are defined by the invention and unclear as to whether the activity falls within one/more than one/none of the above IUBMB enzyme classifications (EC) (for example side-by-side comparisons of structure and function, to

Art Unit: 1651

identify unifying or differentiating features of the claimed compound versus the known enzymes, etc), the metes and bounds of the claims cannot be determined rendering the claims indefinite.

The claimed property of “28kDa (calculated by SDS-PAGE)” is indefinite. It is unclear if Applicant intends to claim a holoenzyme which has molecular weight (MW) of at least 72kDa (prior to gel filtration), of 72kDa (the product of gel filtration) which further has a subunit of 28kDa MW (the product of SDS-PAGE), or if Applicant intends to claim the subunit/monomer itself as the active phenol oxidase. Each is reasonable interpretations of the claims and each defines a distinct invention such that one would not be able to determine the metes and bounds and claims, rendering the claims indefinite.

The term “optimum pH” is indefinite. The term “optimum” is a relative term and it is unclear what defines an enzyme having an “optimum pH” *per se*. Wherein optimal pH refers to an enzyme having optimal enzyme *activity* in the specified range, optimal enzyme activity towards a substrate for that enzyme may be assessed comparing a range of pH for a specific substrate at a constant temperature *or* over a range of temperatures at a constant pH/in a solvent. The instant claims do not require enzyme *activity* or any temperature, substrate, or solvent-system and the specification does not define how one would measure an “optimal pH” *per se*. Given the myriad of possible conditions in which (and substrates against which) optimum pH may be tested, it is unclear which phenol oxidase compositions possess optimum pH between 5.0 and 7.0 *per se*. One would not be apprised as to the compounds embraced by the instant claims, one would not be able to determine the metes and bounds of the claims, thus rendering the claims indefinite.

Art Unit: 1651

Claims 4 and 5 recite the limitation “the basidiomycete belonging to the genus *Flammulina*/*F. velutipes*)” of claim 1. There is insufficient antecedent basis for this limitation in the claims as the limitation is not recited in claim 1. Claims 4 and 5 are improperly drawn to claim 1, rendering the claims indefinite. Amending claim 5 to depend upon claim 4 and claim 4 to depend upon claim 3 would be sufficient to overcome this ground of rejection. For the sake of compact prosecution, claim 5 is being treated as depending from claim 4 and claim 4 as depending from claim 3; however, this does not absolve Applicant from the requirement to amend the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The claims are generally drawn to a neutral phenol oxidase. The dependent claims are further drawn to a phenol oxidase from *Flammulina* including *F. velutipes* including *F. velutipes* strain IFO 30601.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by NISHIZAWA. (Nishizawa, K., et al. Mycoscience 2003, 44, pages 19-23.).

NISHIZAWA teaches the organism *F. velutipes* IFO 30601, raised as a pure culture on potato dextrose agar and on cedar-sawdust-rice bran medium (“Organisms”, page 19). The organism and/or the pure culture is of the same strain as the organism of the instant claims, which absent evidence to the contrary, the *F. velutipes* IFO 30601 taught by Nishizawa would

Art Unit: 1651

inherently produce and possess the same phenol oxidase as the *F. velutipes* IFO 30601 of the instant claims.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by SCHANEL (Biol.Plant., Acad. Sci. Bohemoslov. 1966, 8(4)292-8.(Abstract)) or LAN (Lan, Rui-Fang. Fujian Shifan Daxue Xuebao, Ziran Kexueban. 2002, 18(3),58-60.(Abstract)) or LEE (CA: PTO-1449, 6/21/2005)

SCHANEL and LAN each teach a phenol oxidase enzyme (laccase) which is produced by a *Flammulina velutipes* (formerly assigned to *Collybia velutipes*), which appears to be the phenol oxidase of the claimed invention and would intrinsically have the properties claimed. Lan also teaches extraction of the enzyme.

LEE teaches a *F. velutipes* laccase having pH stability in the range of 5-8 (figure 2; optimally approximately around 6.6 in citrate or Clark Lub's buffer) and temperature stability around 40°C (50% at 60°C, figure 4).

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by LINDBERG (Lindeberg, G. Physiologica Plantarum. 1948, 1, 196-205.(Abstract)).

LINDBERG teaches a phenol oxidase (o-phenol oxidase) which is produced by a *Flammulina* (formerly assigned to *Collybia*), which appears to be the phenol oxidase of the claimed invention and would intrinsically have the properties claimed.

Claim 1, 9, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by KIISKINEN (CA: PTO-1449 8/17/2006, Kiiskinen, et al. Appl Microbiol Biotechnol. 2002, 59, 198-204.)

Art Unit: 1651

The general teachings of the claims are above. Further, the claims are drawn to an enzyme having an optimum pH between 5.0 and 7.0, reacting with (oxidation of) 2,6-dimethoxyphenol among other substrates. The dependent claims are also drawn to a composition comprising the neutral phenol oxidase.

Kiiskinen anticipates the claims, teaching a phenol oxidase comprising a broad optimum pH between 5 and 7.5 (vs. guaiacol; and between 6 and 7 vs. syringaldazine) and catalyzing a reaction with a dye, including 2,6-dimethoxyphenol (column 1, page 199).

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by ECHIGO (JP 09-206071 A, Machine Translation).

The general teachings of the claims are above.

Echigo anticipates the claims, teaching a phenol oxidase (polyphenol oxidase) with an optimum pH in the given reaction conditions of approximately pH 7 (claim 2; Drawing 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The claims are generally drawn to a neutral phenol oxidase as presented above. The dependent claims are further drawn to a phenol oxidase from *Flammulina velutipes*.

Claims 1, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmieri (Appl. Microbiol. Biotechnol. 1993, 39(4/5), pages 632-6.) and FARRELL (Phil. Trans R. Soc. Lond A. 1987, 321, 549-553.).

The general teachings of the claims are above.

Art Unit: 1651

Palmieri teaches a basidiomycete (*Pleurotus ostreatus* (Order: *Agaricales*) phenol oxidase, which has a pH 5.0-7.0 optimum activity (for example activity after 5hrs incubation, 25 °C, pH 5-7, versus at lower pH: ¶1, page 635) which appears to be similar to the claimed phenol oxidase. Furthermore, Palmieri teaches decoloration of dye compositions (decoloration of bleach plant effluents, page 632), which Farrell further supports in teaching industrial applications of lignin-transforming fungal enzymes including reducing (as in decreasing the prevalence of) the chromophoric groups in lignin bleaching, reduction of brightness inversion, and decolorization (abstract, page 549; industrial applications, page 552).

The cited reference discloses a composition comprising an enzyme which appears to be identical to the presently claimed composition, since it was isolated from a relate basidomycete fungus which produces a phenol oxidase with the same or similar properties. Although the claimed composition (with respect to tested properties, for example: oxidation of *o*-aminophenol, etc at pH 6.5.) is not identical to the referenced composition, with regard to some unidentified characteristics, the differences between that which is claimed and that which is disclosed, is so slight that the referenced composition is likely to inherently possess the same characteristics of the claimed composition, particularly in view of the similar characteristics which they have been shown to share (e.g. ability to react with lignin, etc.). Thus, the claimed composition would have been obvious to those of ordinary skill in the art within the meaning of 35 USC § 103(a).

One would have been motivated to use the enzyme in a dye composition/ composition containing a dye because Farrell teaches the general benefit of using the enzymes in such compositions, such as to decolorize, bleach, etc., also teaching the advantage of displacing chlorine-based oxidizing agents, reducing brightness inversion while maintaining increased pulp

Art Unit: 1651

mechanical strength, etc. (Farrell, page 552). One would also had a reasonable expectation of success in making a dye composition (the non-decolored lignin substrate or veratryl alcohol), since a dye composition treated with fungal lignolytic enzyme is taught be Farrell to retain substrate (ligninase or alcohol-oxidizing) activity. Additionally, compositions comprising a substrate (such as dye), and an enzyme selective for the substrate would be obvious to one of skill and routinely optimized in the art. Thus the claimed dye composition and/or a composition comprising a phenol oxidase enzyme and a dye substrate would be obvious to one of skill.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Claims 1, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over KLEEN (US Patent Application 11/455,4334 as evidence of DE 103.59.577.0).

The general teachings of the claims are above.

Kleen teaches a dye composition comprising an enzyme oxidizing agent including laccase and phenol oxidases including enzymes of *Acremonia*, *Stachybotrys*, or *Pleurotus* origin (§ 133, page 8, column 1) capable of oxidizing a dye including *o*-aminophenol, 4-hydroxyindole, etc (page 5, column 1). Though Kleen does not teach the specific combination of a neutral phenol oxidase with the above dye substrates, Kleen does teach that the enzymes, particularly the laccases (§ 133, page 8, column 1), directly oxidize the dye precursors. Absent evidence to the contrary, the enzyme taught by Kleen appears to be similar or an obvious variant of the enzyme of the instant claims as both Kleen and the instant claims teach/are drawn to an enzyme which is capable of oxidizing dyes, including *o*-aminophenol. Furthermore, it would be obvious to combine the enzyme with a dye that the enzyme is capable of oxidizing, because combining

Art Unit: 1651

enzymes with compounds that are transformed by the enzyme (substrates) is routinely performed in the art.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Please note, since the Office does not have the facilities for examining and comparing Applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product(s) of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980), and "as a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Art Unit: 1651

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The general teachings of the claims are above. The dependent claims further teach a phenol oxidase produced by the fungus, *F. velutipes* IFO 30601.

Claims 1-5 and 9-10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 7,135,184 ("184").

Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim sets disclose the same phenol oxidase enzyme from the same source with the same reactivity. Furthermore, it is noted that the instant claims do not require a distinct isolation of the enzyme and the claims of '184 claim the enzyme both as a culture containing the enzyme and purified to the extent of removing the hyphae from the culture.

No claims are allowed.

Conclusion

Please note, the references of LINDEBERG, SCHANEL, and LAN cited above are not presently available to the Examiner, but will be provided to the extent available in the subsequent office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron J. Kosar whose telephone number is (571) 270-3054. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday, EST.

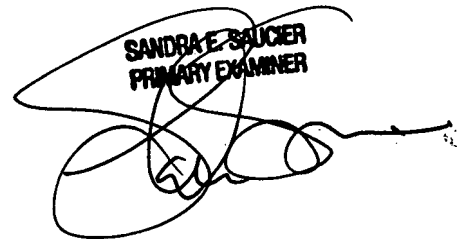
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1651

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Aaron Kosar
Examiner
Art Unit 1651



SANDRA E. SAUCIER
PRIMARY EXAMINER